REMARKS/ARGUMENTS

Applicants gratefully acknowledge the acceptance of our request for continued examination of this application filed on 8/8/2006 under 37 C.F.R. § 1.114; the acceptance of our terminal disclaimer filed on 8/8/2006, and subsequent withdrawal of the provisional rejection of claims 1-4 under the doctrine of obviousness-type double patenting over co-pending Application No. 10/363,484.

Prior to this Amendment, Claims 1-17 were pending in this application. Claims 5-14 were previously withdrawn from consideration. With this Amendment, Claim 17 is canceled herein. Thus, Claims 1-4, 15 and 16 are presented for further prosecution.

Claims 1, 3, 4, 15 and 16 are amended herein. Basis for these amendments is found throughout the specification and claims as originally filed. For example, basis for the amendments to claims 1, 15 and 16 can be found on page 20, lines 11-13 and page 25, line 10. Basis for the amendments to claim 4 is found in the specification and claims as originally filed. Finally, the amendments to claims 3 and 16 correct minor typographical errors. No new matter has been added.

Applicants respectfully request the Examiner to mark off the cited references in the next Office Action.

Claim Rejections - 35 USC § 102

The Action has maintained the rejection of claims 1-3 and 15-17 under 35 U.S.C. § 102(a) as allegedly being anticipated by Lederer, et al. (*J. Agric. Food Chem.* 47:4611-4620, 1999); and Quinton, et al. (Tetrahedron Letters 32:4909-4912, 1001). Further, the Action has maintained the rejection of claims 1-4, 15 and 16 under 35 U.S.C. § 102(b) as allegedgly being anticipated by Miyaichi, et al. (Nature Medicines, 49:24-28, 1005); and Hamberg, et al. (Plant Physiology, 110:807-815, 1996). Applicant respectfully disagrees.

As amended herein, the invention as defined by the claims, distinguishes over the cited references by claiming pharmaceutical compositions comprising a purified or synthesized hydroxy unsaturated fatty acid as an active ingredient and a pharmaceutically acceptable carrier, wherein the hydroxy unsaturated fatty acid is an unsaturated fatty acid with 18 carbon atoms and the unsaturated fatty acid may be substituted at its hydroxyl group or a carbonyl group of a carboxylate moiety, wherein the purity of the hydroxy unsaturated fatty acid is 95% or higher.

None of the cited references disclose pharmaceutical compositions of hydroxy unsaturated fatty acids as an active ingredient and a pharmaceutically acceptable carrier as required by the instant claims. Instead, in Lederer, the fatty acids are in solvents such as pyridine, N,N-dimethylformamide and diethyl ether; in Hamberg, the fatty acids are in a solvent such as methanol/chloroform, in Miyaichi, the fatty acids are extracted with methanol; and in Quinton, the fatty acids are produced in solvents such as benzoyl chloride, pyridine/dichloromethane, and potassium carbonate in methanol/water. The above solvents disclosed in combination with the hydroxy unsaturated fatty acids are unacceptable for administration to a subject for any medicinal purpose, i.e., the fatty acids are in solutions/solvents/buffers which are not pharmaceutically acceptable carriers.

In response to our previous arguments, the Action asserts that the use of the term "pharmaceuticals composition" is deemed to be an intended use and hence does not constitute a claim limitation. Applicants respectfully disagree.

According to the MPEP § 2111.02, "the determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim." It further states that "during examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim."

Applicants submit that the term "pharmaceuticals composition" does not merely recite the intended use of the claimed invention. In the absence of the term "pharmaceutical," a "composition comprising ....." may contain a toxic substance having no pharmacological effect. The existence of the term "pharmaceutical" excludes the inclusion of such a toxic substance. As such, the term defines a structural difference between claimed invention and the prior art such as Lederer and Quinton which disclose compositions containing a toxic solvent having no pharmacological effect.

The Action also states that Lederer discloses that the disclosed compositions are being tested in biological systems which would allegedly require them to be acceptable for administration to a subject, quoting the following sentence: "Further investigations are in progress to transfer the experiences of the model study to biological systems and to either verify or disprove the hypotheses outlined here" (see, page 4619, left column, lines 8-4 up).

Similarly, the Action contends that Quinton discloses that the biological activities of the disclosed compositions are being tested which would allegedly require them to be acceptable for administration to a subject and quotes the following sentence: "The biological activities of these compounds are currently under investigation"(see, page 2912, line 1).

Apart from these quoted sentences, there is no mention in either Lederer or Quinton as to what experimental systems are being used. One skilled in the art could not have predicted whether compositions used in unknown experimental systems are acceptable for administration to a subject.

Lederer discloses unsaturated fatty acids 14 and 15 (see, page 4614, right column), which are encompassed by claim 3 of the instant application, as hydrolysis products of epoxyhydroxyoctadeeoenoate (compounds 11a, b). If the hydrolysis is conducted using microbial experimental systems, the hydrolysis products may be produced in microbial cells. In this case, it cannot be said that any microbial cells or cell extracts containing the hydrolysis products are acceptable for administration to a subject.

Similarly, Quinton does not suggest what experimental systems are being used. From the above quotation from Quinton, none of the skilled artisans could have predicted what composition is used in the experiment and whether the composition is acceptable for

administration to a subject. Quinton discloses that unsaturated fatty acids were isolated from a variety of rice plant, Sasanishiki, suffering from the rice blast disease and shown to be active against the fungus (see, page 4909). As biological activities of the fatty acids, only anti-fungal activity is mentioned. Antifungal activities are usually evaluated by disk diffusion methods. If a disk diffusion method is used to assess antifungal activity of the unsaturated fatty acids disclosed in Quinton, compositions containing the fatty acids may also include a fungal culture. Such compositions cannot be said to be acceptable for administration to a subject.

As discussed above, neither Lederer nor Quinton disclose the claimed compositions containing the fatty acids, which are acceptable for administration to a subject. These references disclose the fatty acids in inorganic or organic solvents, but not in pharmaceutically acceptable carriers such as water. The Action's assertion based on the quoted sentences is merely speculative and is not supported by any evidence. Accordingly, the claimed invention is not anticipated by Lederer and Quinton and the rejection should be withdrawn.

Furthermore, Lederer discloses that compounds 14 and 15 could not be completely separated and products contained 14 and 15 in 3:1 and 2:1 ratio, respectively (see, page 4615, left column, lines 7-12). As amended herein, the claims are directed to pharmaceutical compositions comprising the unsaturated fatty acid having the purity of 95% or higher. Such compositions are not anticipated by the disclosure of Lederer.

Regarding Miyaichi, the Action asserts that the disclosed herb comprises the claimed compound and is acceptable for administration to a subject. The currently claimed composition comprising the unsaturated fatty acid having the purity of 95% or higher does not include the herb containing unpurified fatty acid. Miyaichi also discloses roughly purified fatty acid which was obtained by purification steps including methanol extraction, ethanol extraction, silica gel chromatography, and recrystallization (see pages 25-26). In contrast, according to the present application, the fatty acid is isolated and purified used more complicated procedure to achieve such a high purity as 95% as described in the instant specification at pages 9-10, and Examples 1 and 2. Thus, the claimed invention is not anticipated by the disclosure of Miyaichi.

The Action also contends that Hamberg disclose oak seeks comprising the claimed fatty acid, which are acceptable for administration. For the same reasons as described

above, oat seeds including unpurified fatty acids are excluded from the claims which are drawn to a pharmaceutical composition comprising the unsaturated fatty acid having the purity of 95% or higher. Apart from oat seeds, Hamberg does not disclose any composition containing the fatty acid with the purity of 95% or higher.

As discussed above, none of the prior art references disclose the claimed pharmaceutical composition comprising the fatty acid with the purity of 95% or higher. Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections.

Claim Rejections - 35 USC § 112

1st paragraph

The Action has rejected claim 17 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As amended herein, claim 17 has been canceled which renders the rejection of this claim moot. Applicants respectfully request reconsideration and withdrawal of this rejection.

2nd paragraph

The Action has objected claim 4 under 35 U.S.C. § 112, second paragraph for allegedly lacking sufficient antecedent basis for reciting "prepared from a medicinal plant" in line 1.

As amended herein, dependent claim 4 recites "purified from a medicinal plant" in line 1, which provides proper antecedent basis from claim 1. Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (858) 350-6155.

Respectfully submitted,

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